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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,728	03/01/2000	Thomas O Daniel	1242/12/2	2723
25297	7590	10/05/2004	EXAMINER	
JENKINS & WILSON, PA 3100 TOWER BLVD SUITE 1400 DURHAM, NC 27707			YAEN, CHRISTOPHER H	
		ART UNIT	PAPER NUMBER	
		1642		

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/516,728	DANIEL ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 April 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 56-61 and 63-92 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 56-61 and 63-92 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Re: Daniel et al
Priority Date: 01 March 2000

1. The amendment filed 4/15/2004 is acknowledged and entered into the record. Accordingly, claims 1-55, and 62 are canceled without prejudice or disclaimer, and claims 90-92 are newly added.
2. The declarations filed 4/15/2004 is acknowledged and entered into the record.
3. Claims 56-61,63-92 are pending and examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 103

5. The rejection of claims 56-58,60-61,68-73,76-79, 81-82 and now new claims 90-91 under 35 USC § 103(a) is maintained for the reasons of record. Applicant argues the references combined do not suggest or teach all of the limitations of the currently amended claims. In particular, the claims have been amended to reflect an isolated antibody that binds to an amino acid sequence found within the extracellular domain of ECRTP/DEP-1, wherein the antibody is in a diluent or excipient pharmaceutically acceptable in humans. Applicant further argues that Tonks *et al* discloses PTPs in general and describes the use of PTPs as a class for further study or "invitation to explore a branch of research involving the various members of the PTPase family." Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The suggestion or motivation to combine the Honda *et al* reference and the Tonks *et al* reference resides in the fact that Tonks *et al* does in fact teach different antibody types against the DEP-1 protein as currently claimed. For example, on page 8 of Tonks *et al* it clearly indicates that binding peptides to DEP-1 are also desired, wherein the peptides can be antibodies (i.e. monoclonal, polyclonal, chimeric, etc. – see page 8 of Tonks *et al*). Thus contrary to what applicant has argued, the Tonks *et al* reference does not teach a general class of PTPs as stated but rather specifically discloses certain embodiments of DEP-1, which is a type or species of PTPase. Furthermore, the suggestion or motivation for combining the isolated antibody with a pharmaceutical excipient or diluent for use in human comes from the fact that Tonks *et al* disclose that the antibodies can be used for *in vivo* modulation (see page 9, lines 1-2) and it would be *prima facie* obvious to one of ordinary skill in the art to use excipients that are compatible for human use because the purpose of modulation is to affect the outcome of a disease in a human.

Claims 90-91 are also rejected because the claims are drawn to the product per se and the intended use of the antibody does not breath any patentable weight into the claims.

Thus, the rejection of claims under 35 USC 103(a) as being obvious is maintained for the reasons of record.

New Arguments

Claim Rejections - 35 USC § 112, 2nd paragraph

6. Claims 56-61 and 63-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regards to claims reciting ECRPT/DEP-1 and dependents thereof, it is vague and indefinite for reciting the term as the sole means of identifying the claimed molecule. The use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. This rejection can be obviated by amending the claims to specifically and uniquely identify ECRTP/DEP-1 by a sequence identification number (SEQ ID No.) and function.

Claim Rejections - 35 USC § 112, 1st paragraph

7. Claims 56-61 and 63-92 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth a human ECRTP/DEP-1 polypeptide of SEQ ID No: 4 and therefore the written description is not commensurate in scope with the claims which read on the broad scope of ECRTP/DEP-1 polypeptides claimed.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The claims recite a "ECRTP/DEP-1" as part of the invention. However, there does not appear to be an adequate written description in the specification as-filed of the essential structural features that adequately describes the genus of ECRTP/DEP-1 polypeptides claimed. The specification teaches that the ECRTP/DEP-1 molecule encompasses fragments of the ectodomain (see page 47, lines 8-12). Additionally, the instant invention also embodies analogs of the ectodomain (see page 47, lines 8-12) of which have not been defined by any structural or functional characteristics. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying

characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Applicant does not appear to have reduced to practice with exception to SEQ ID No: 4 any other sequences that are encompassed by the term ECRTP/DEP-1. Neither has Applicant provided a sufficient written description of any structure that may be correlated with the desired function of the ECRTP/DEP-1 polypeptide. Thus the genus of compounds encompassed by this term is extensive and the artisan would not be able to recognize that Applicant was in possession of the invention as now claimed. In addition, as noted supra "ECRTP/DEP-1" is an indefinite term and therefore the structure of a "ECRTP/DEP-1" is also not described.

Consequently, Applicant was not in possession of the instant claimed invention.

See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol.

66, No. 4, pages 1099-1111, Friday January 5, 2001. Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 4/15/2004.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
September 27, 2004



GARY NICKOL
PRIMARY EXAMINER